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Kim

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(54) **SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABILIZATION OF THE SPINE**

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USPC ..... 606/105, 198, 57, 248, 249, 86 A–86 B, 606/90, 914, 99; 623/17.11, 17.12, 17.16, 623/23.67

See application file for complete search history.

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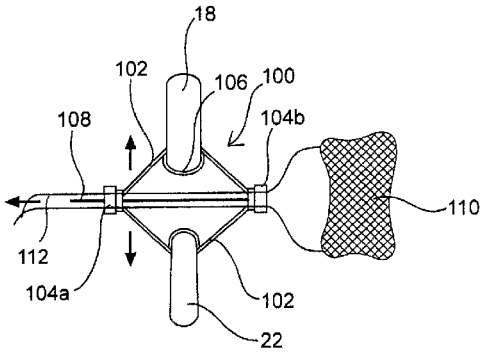
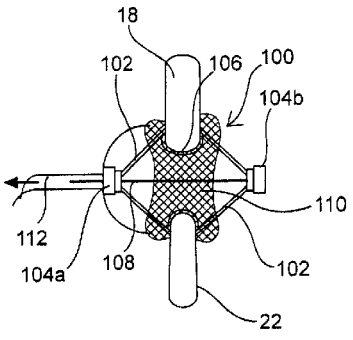
(57) **ABSTRACT**

Devices, systems and methods for dynamically stabilizing the spine are provided. The devices include an expandable spacer or member having an unexpanded configuration and an expanded configuration, wherein the expandable member in an expanded configuration has a size, volume and/or shape configured for positioning between the spinous processes of adjacent vertebrae in order to distract the vertebrae relative to each other. The systems include one or more expandable members and a mechanical actuation means for expanding the expandable member or an expansion medium for injection within or for filling the interior of the expandable member via the port. The methods involve the implantation of one or more devices or expandable spacers.

26 Claims, 19 Drawing Sheets





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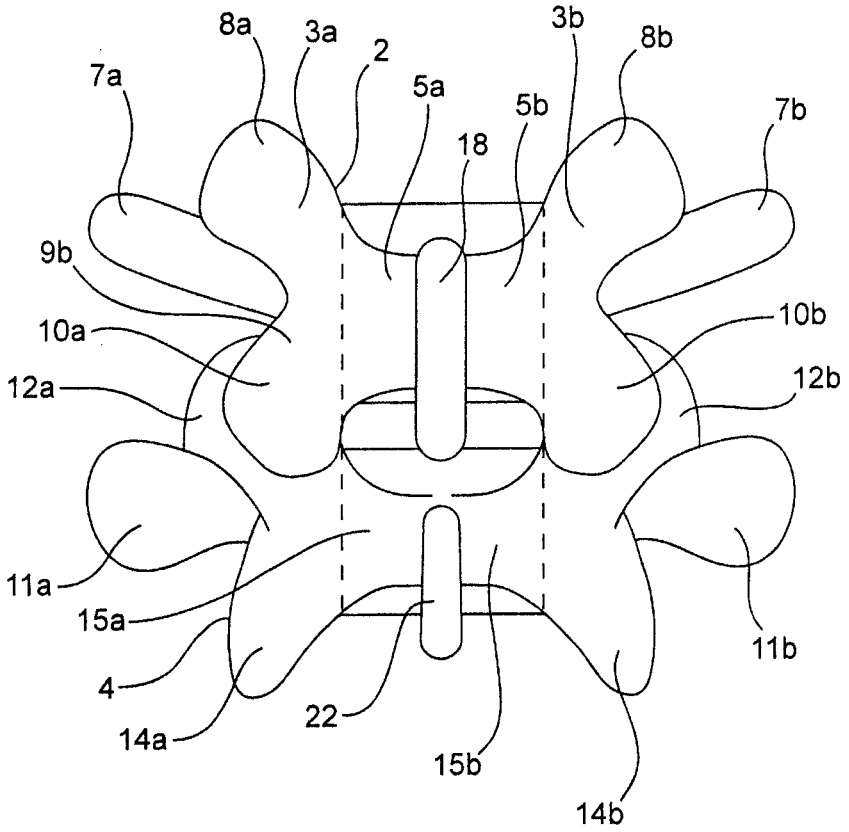
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11b
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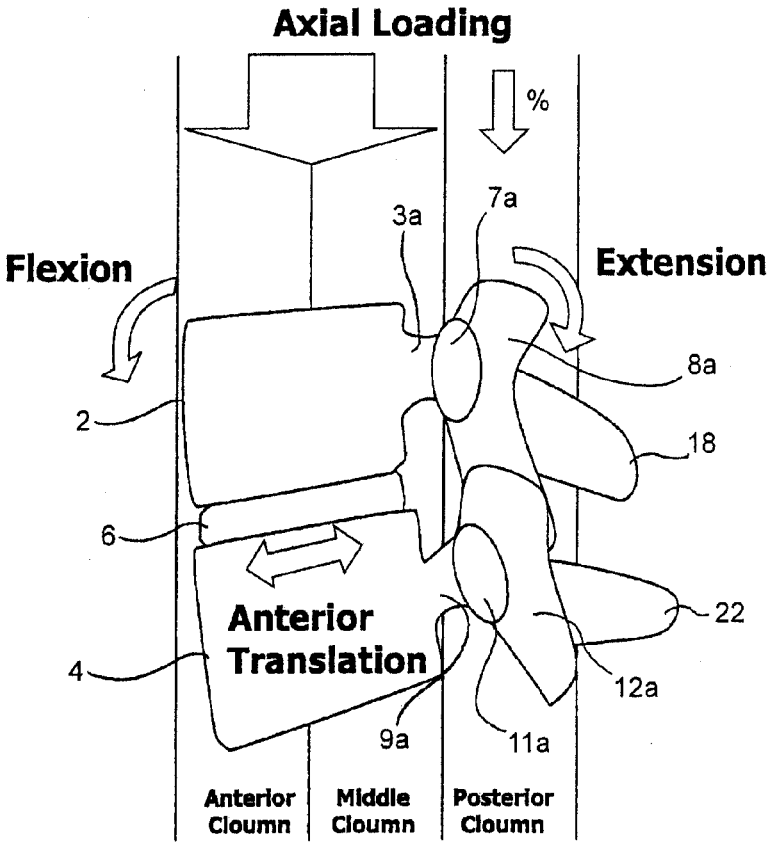
FIG. 1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Cloumn

FIG. 2A

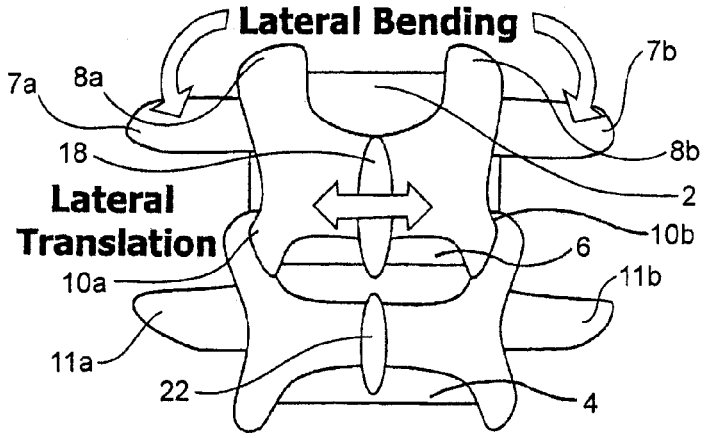
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FIG. 2B

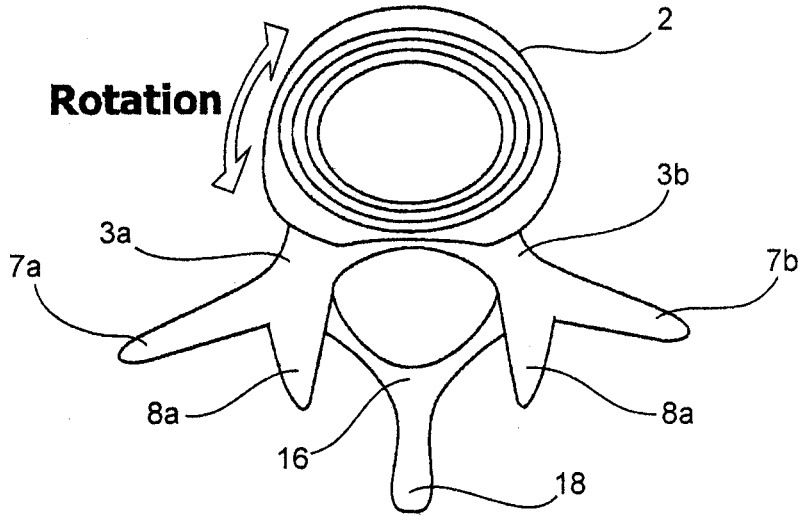

FIG. 2C

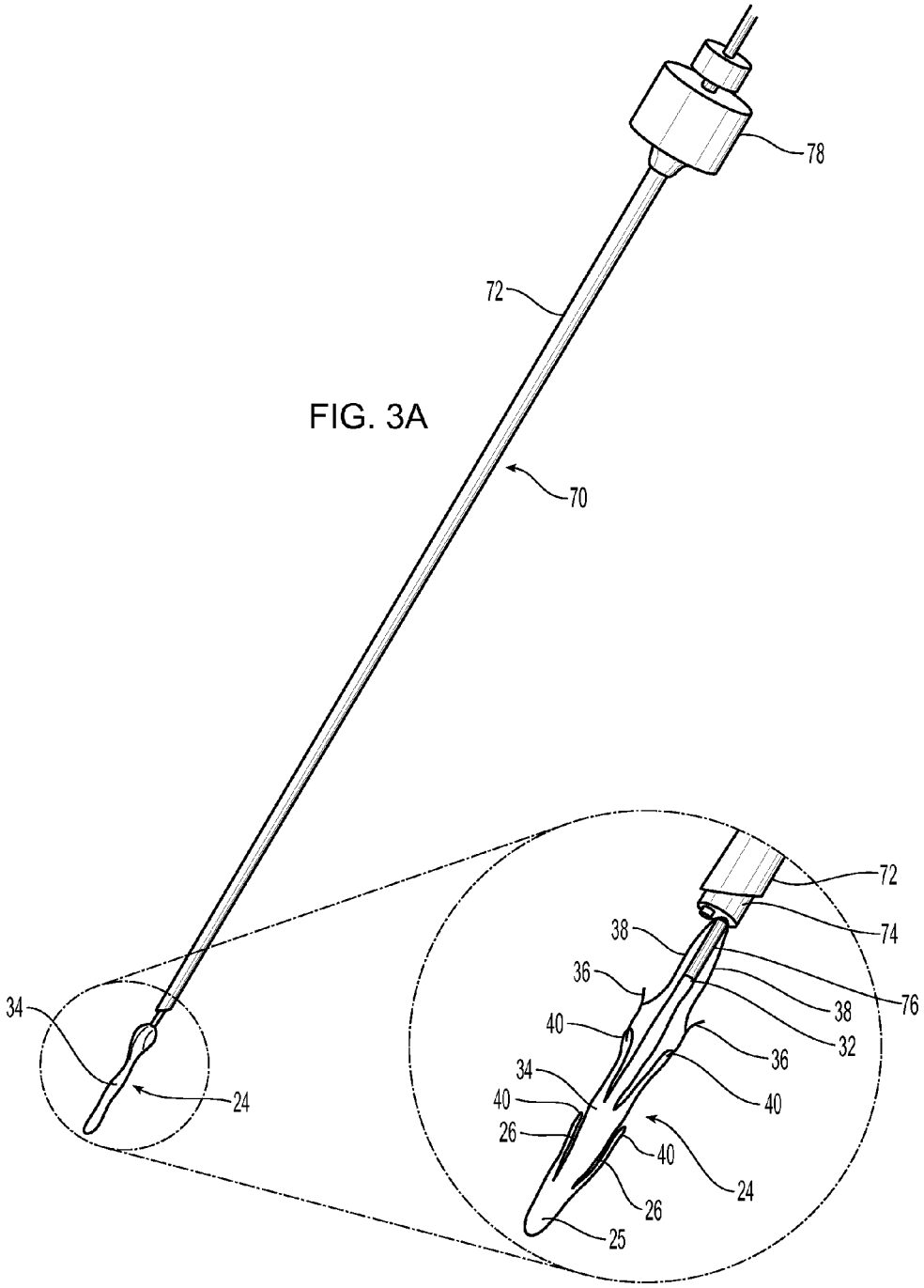

FIG. 3A

FIG. 3B

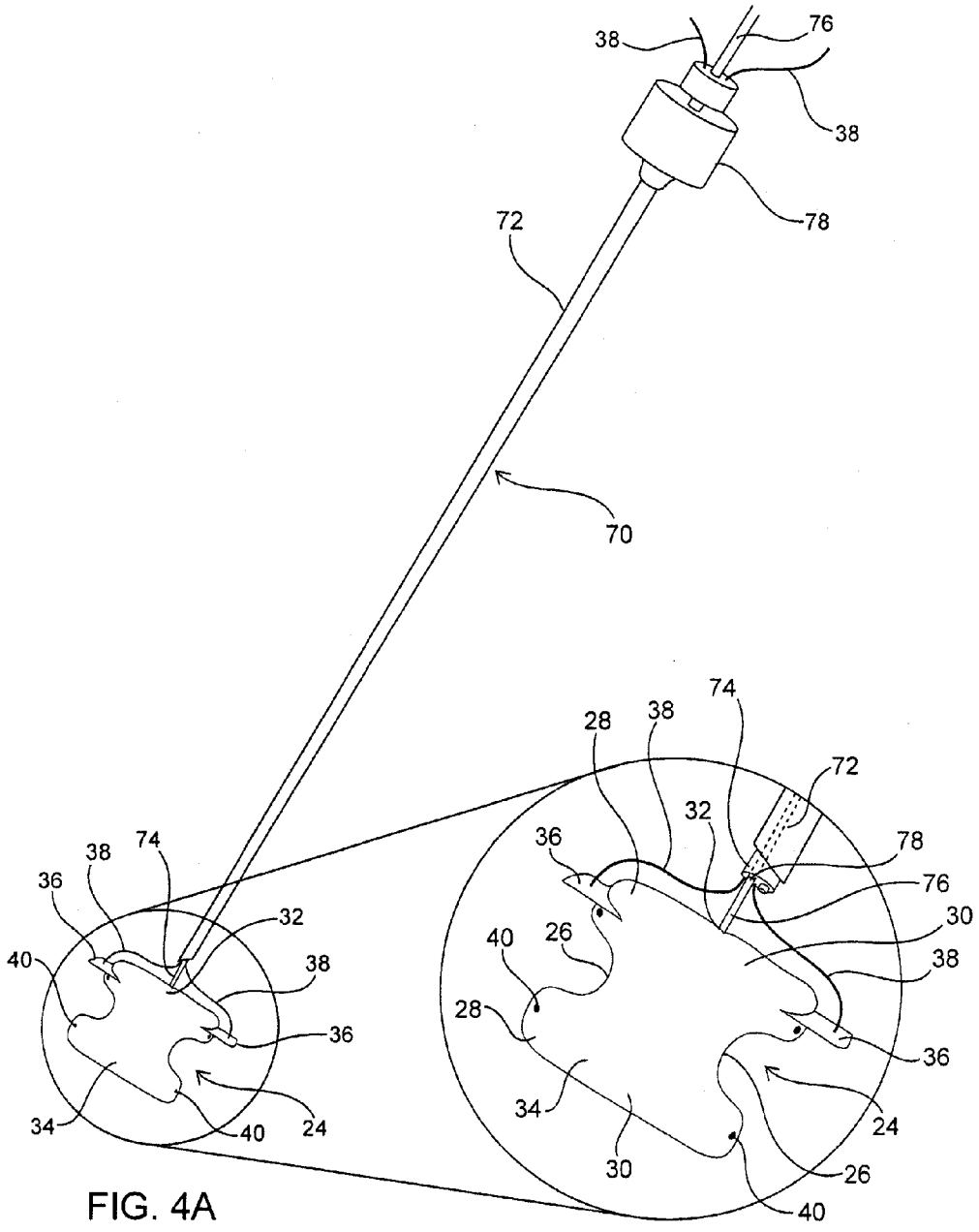
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FIG. 4A

FIG. 4B

FIG. 5A

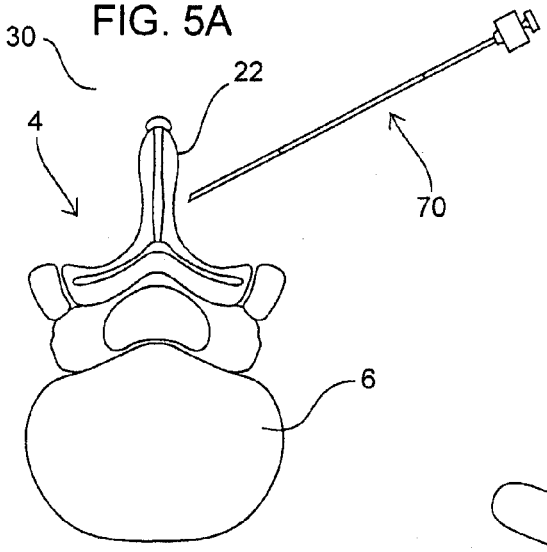


FIG. 5B

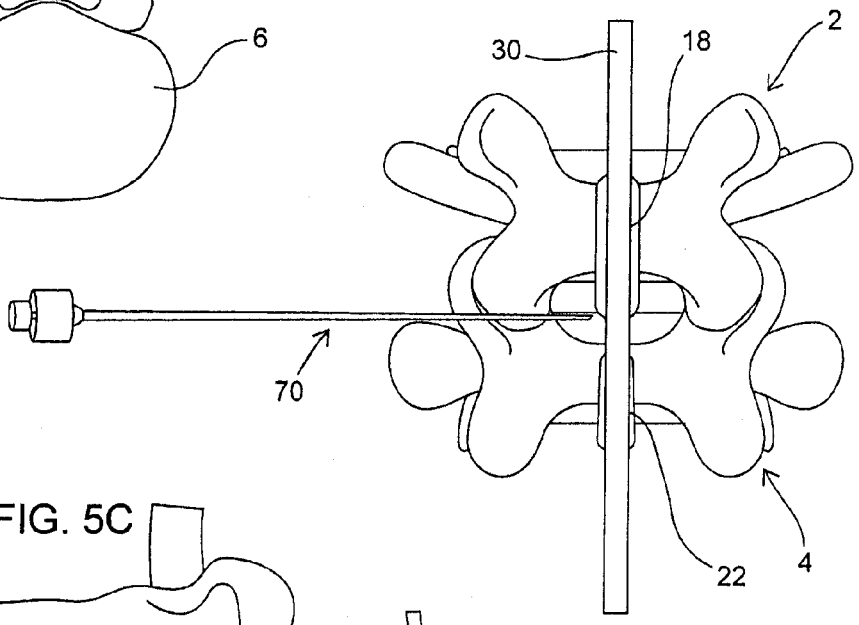
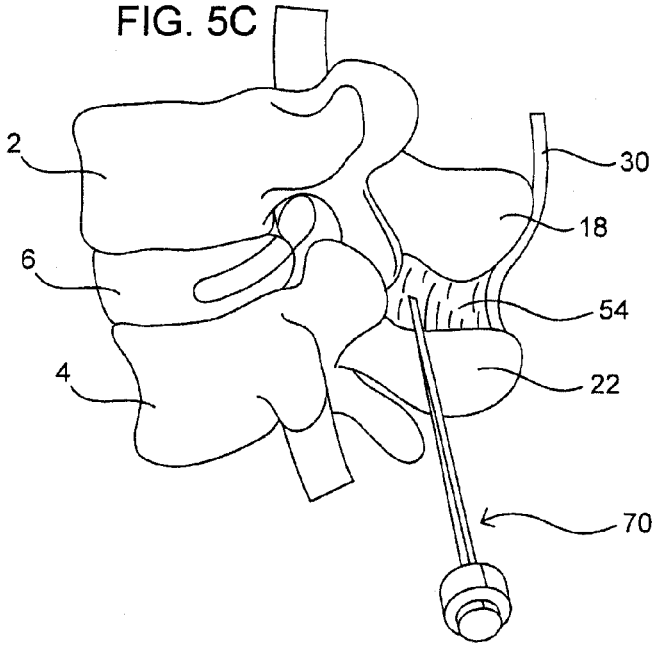


FIG. 5C



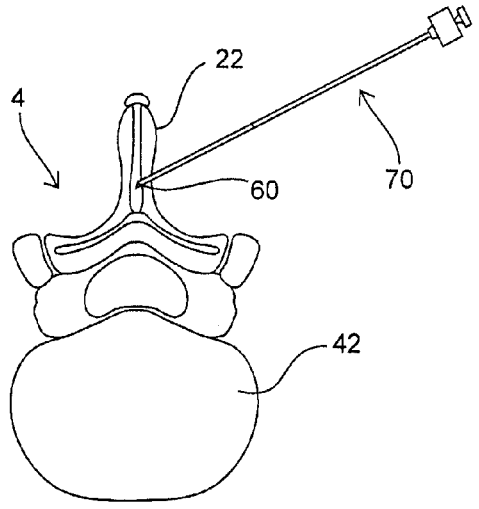


FIG. 6A

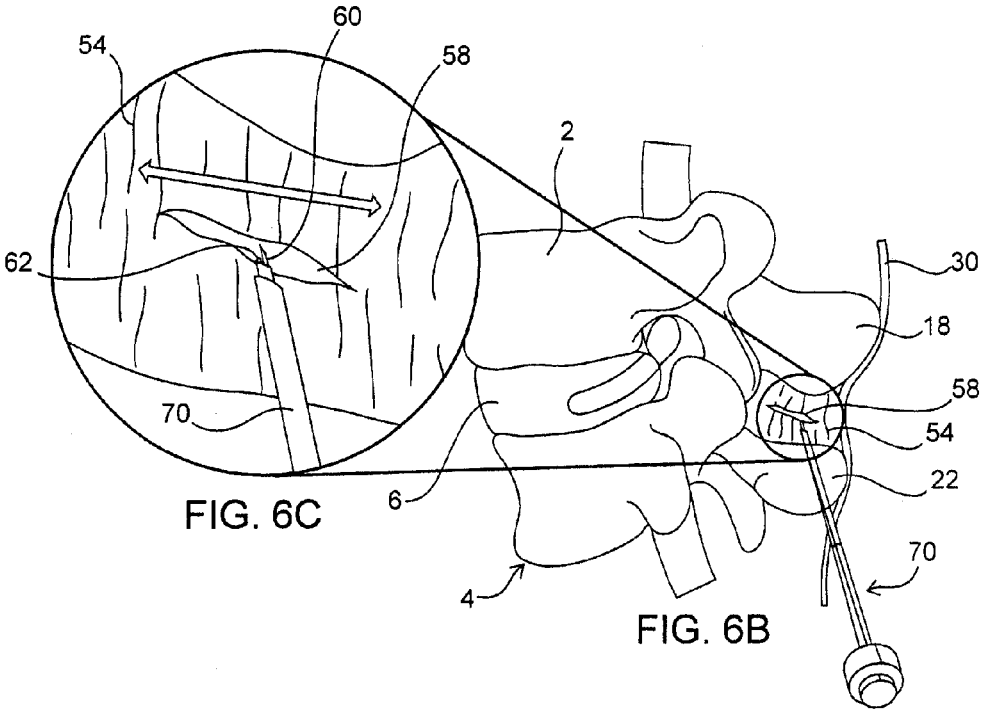


FIG. 6C

FIG. 6B

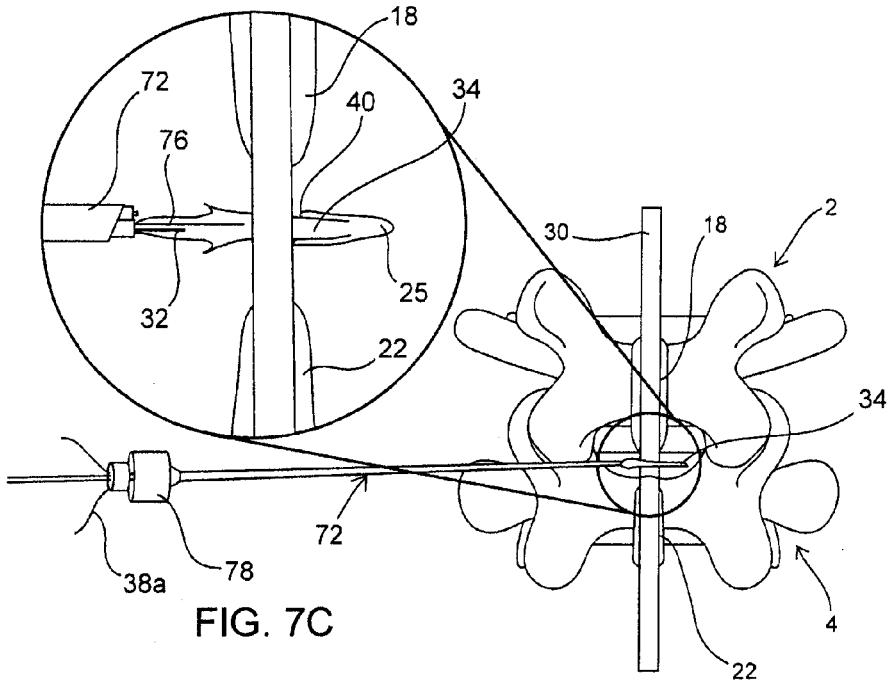


FIG. 7C

FIG. 7A

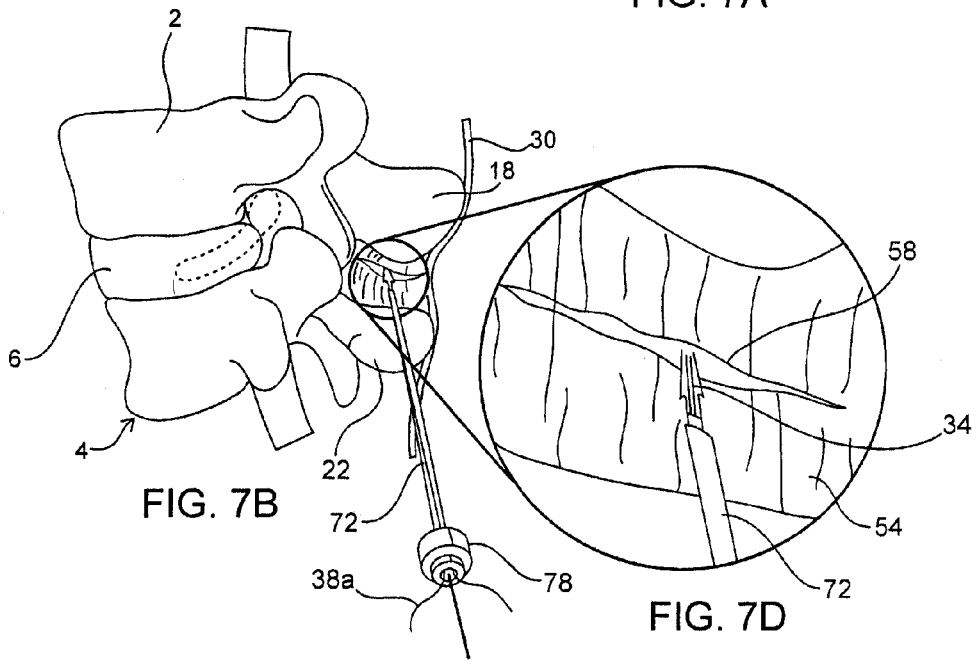


FIG. 7B

FIG. 7D

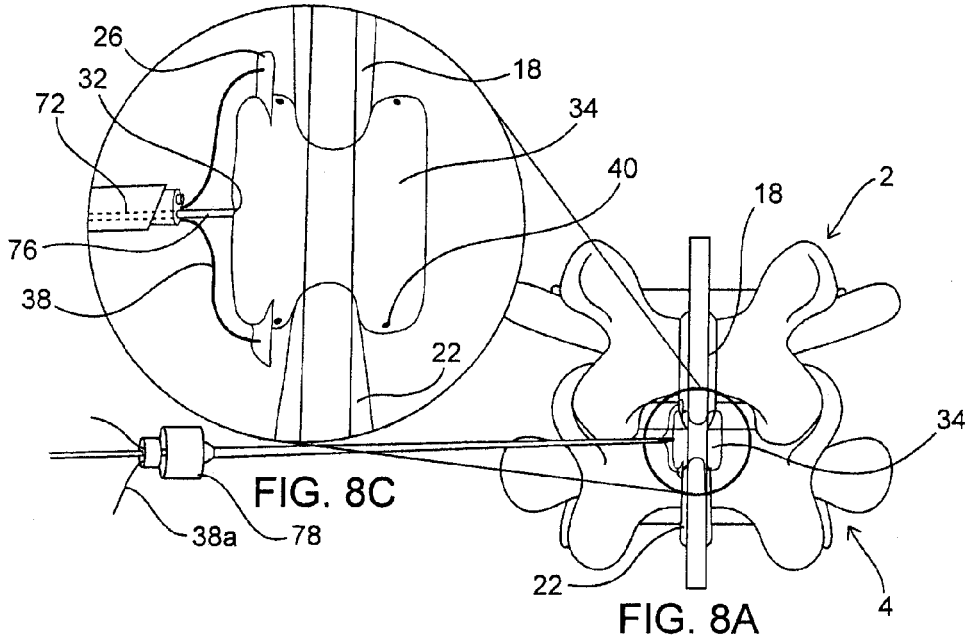


FIG. 8C

FIG. 8A

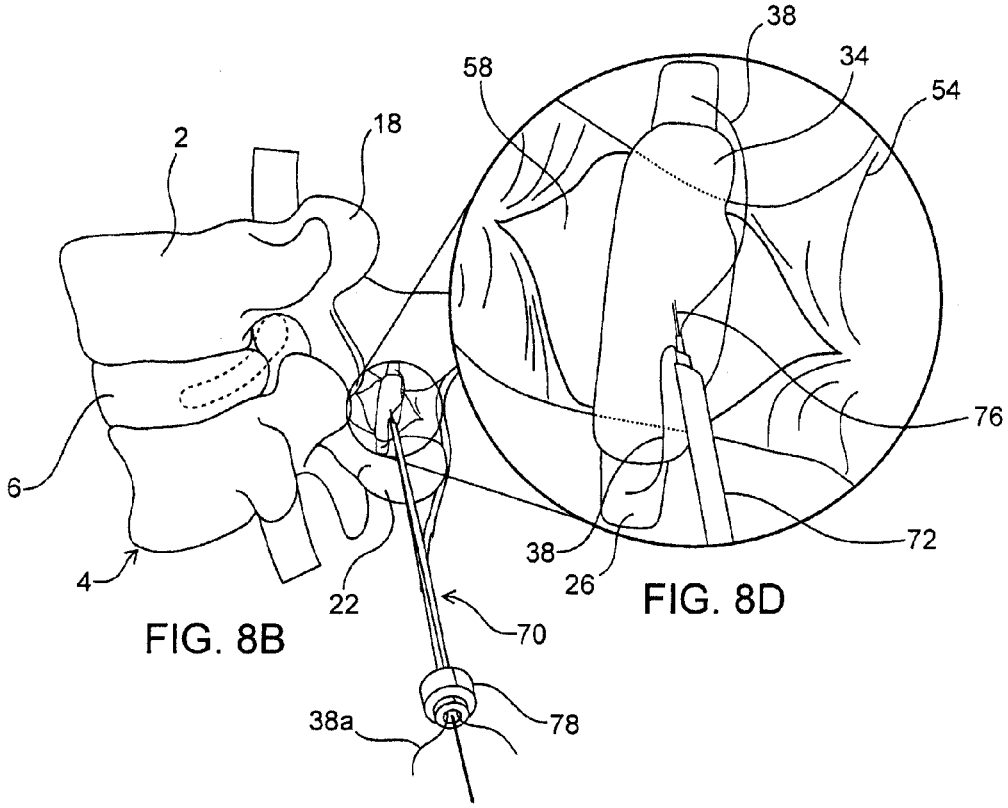


FIG. 8B

FIG. 8D

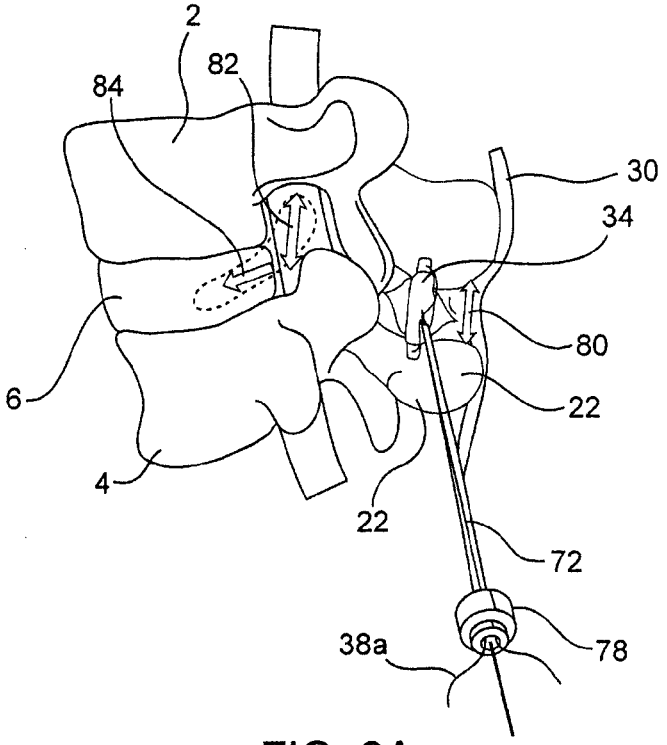


FIG. 9A

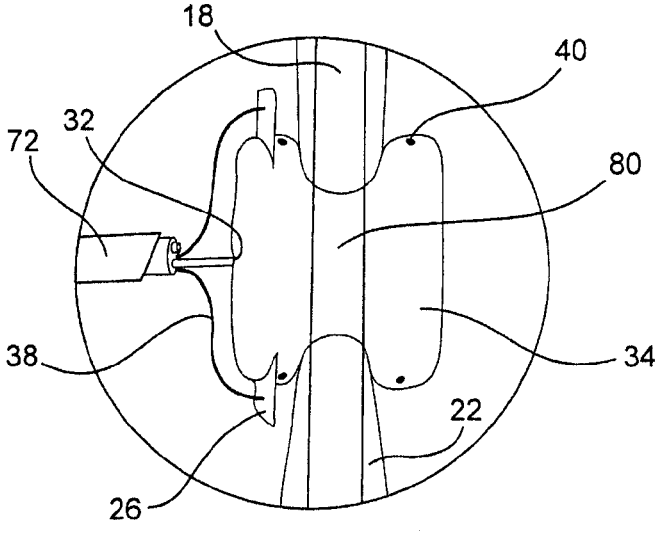


FIG. 9B

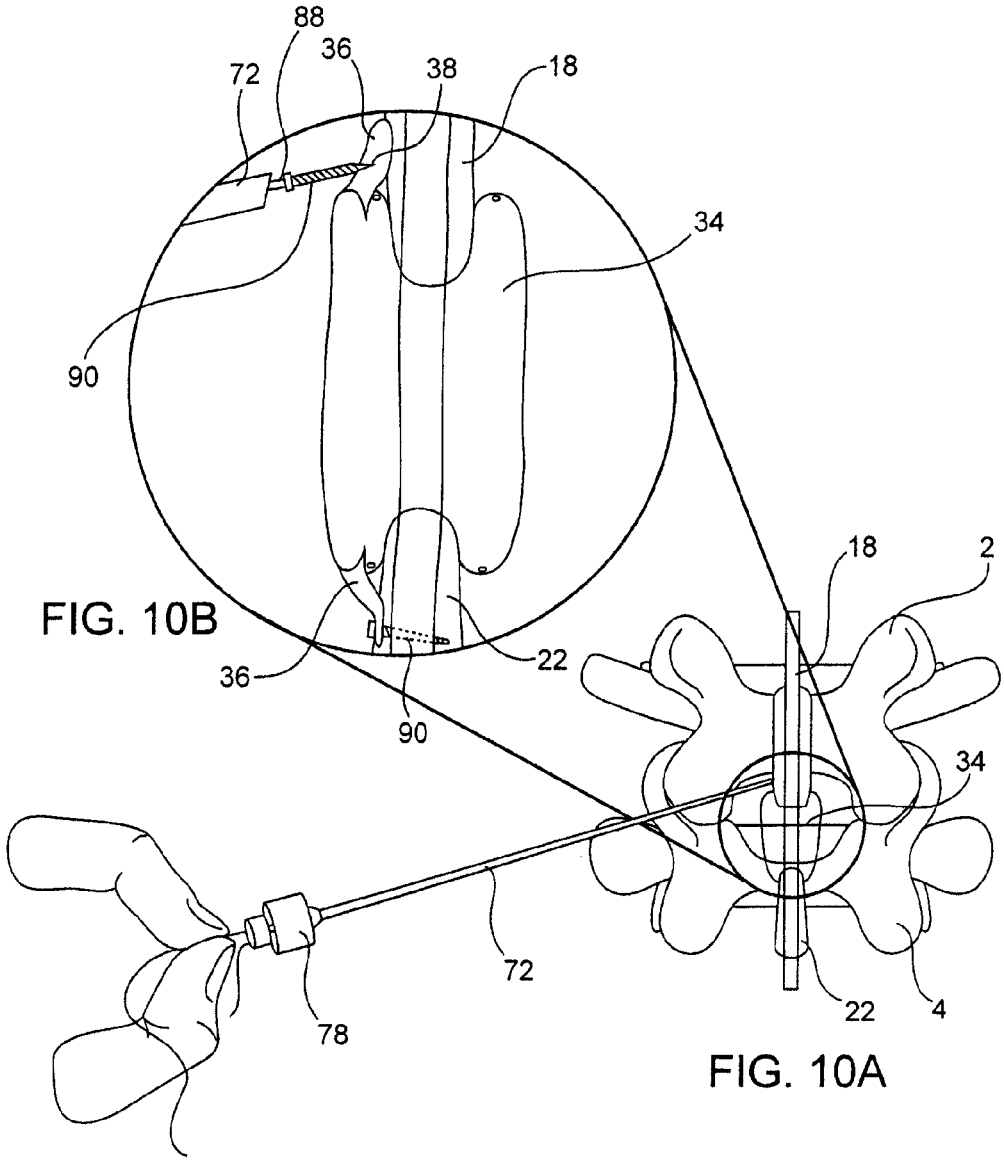


FIG. 10B

FIG. 10A

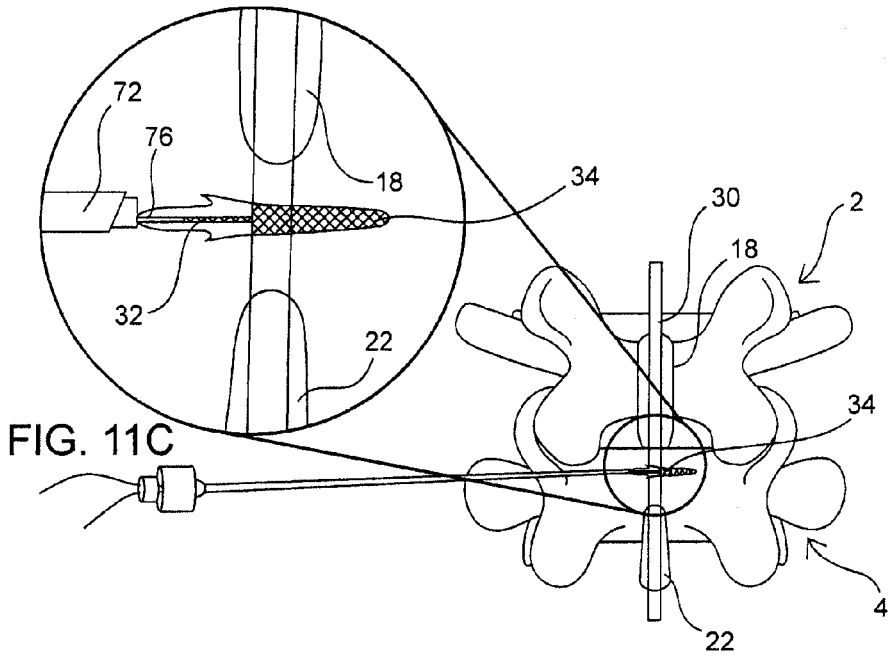


FIG. 11C

FIG. 11A

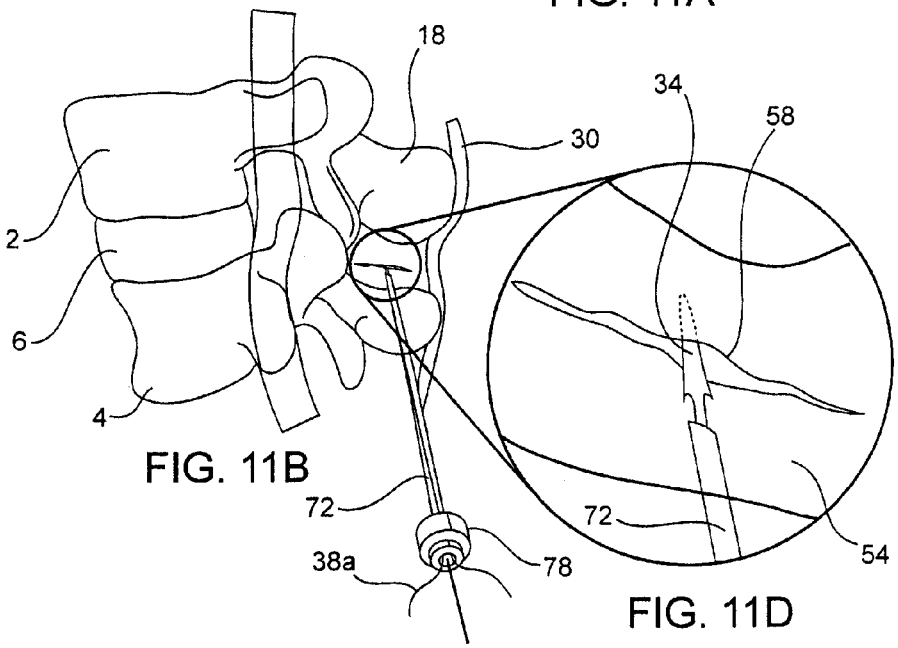


FIG. 11B

FIG. 11D

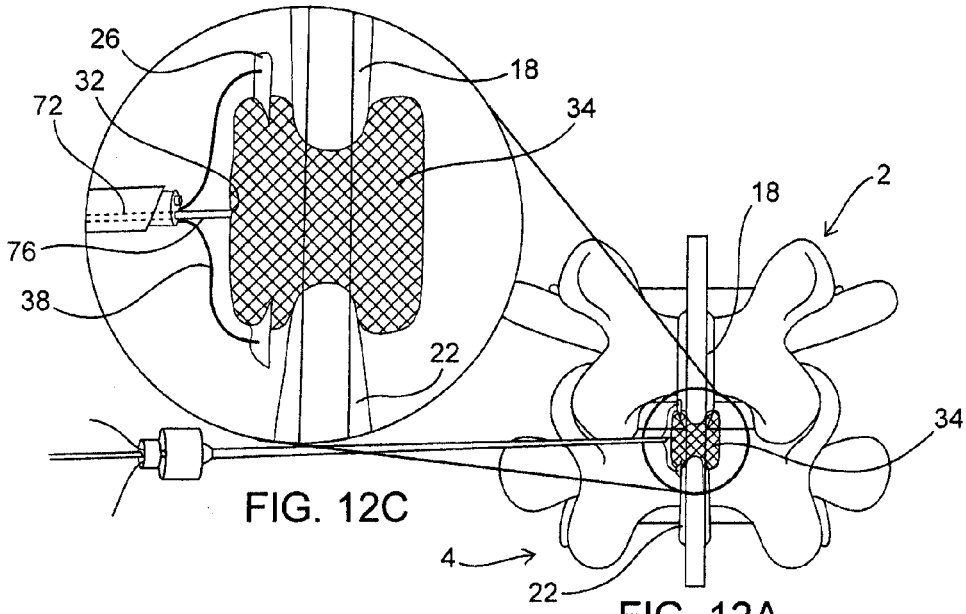


FIG. 12C

FIG. 12A

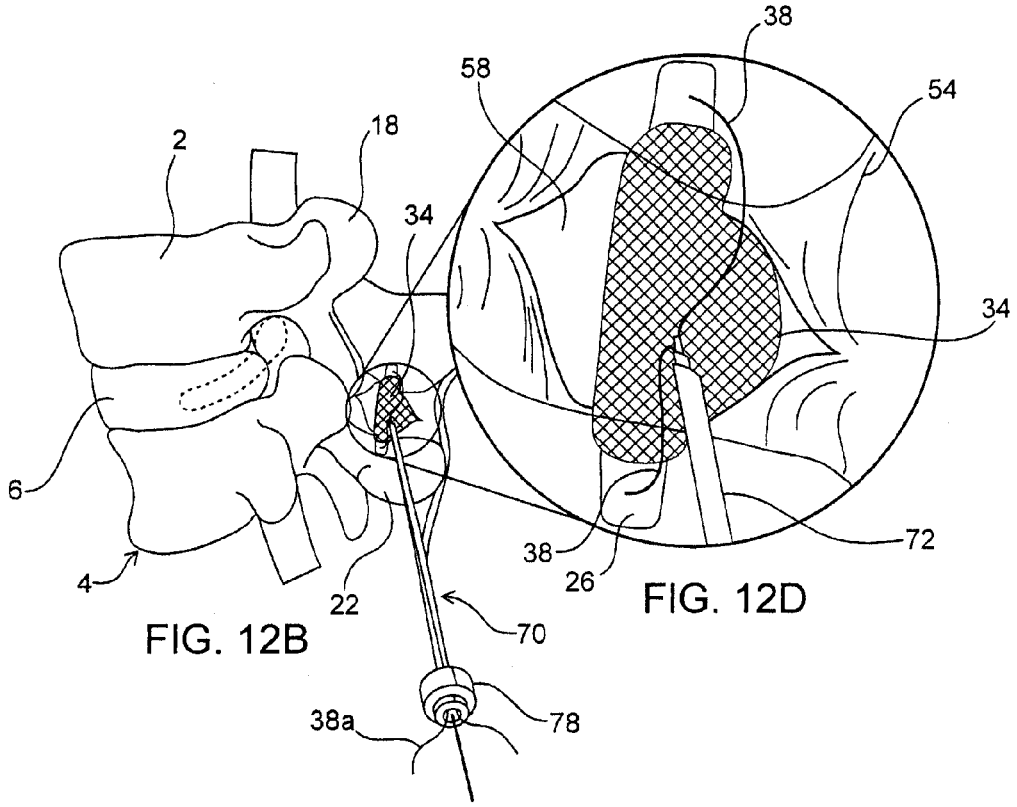


FIG. 12B

FIG. 12D

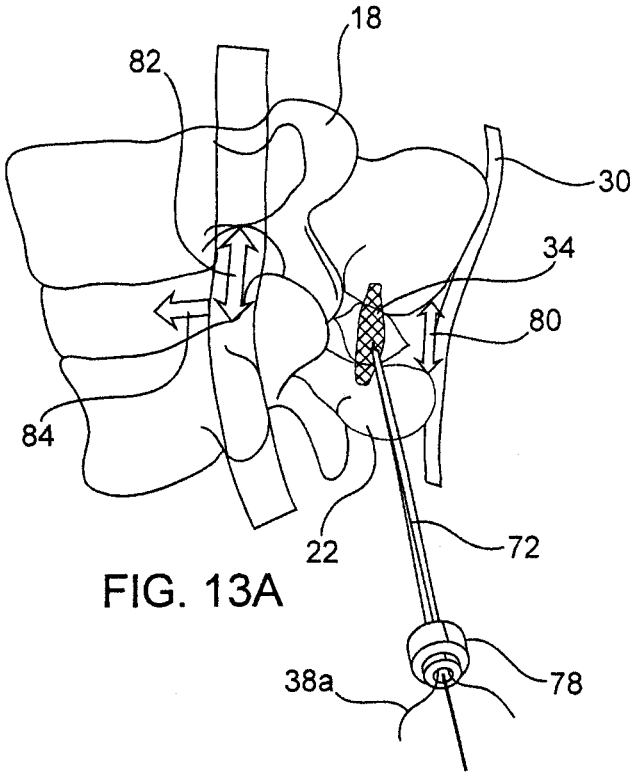


FIG. 13A

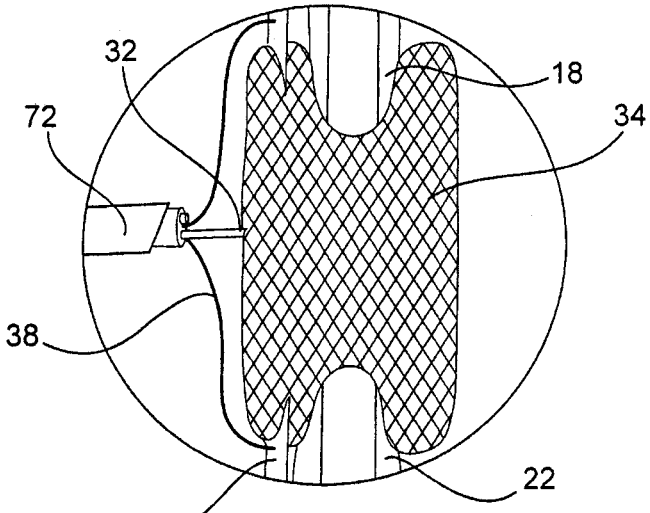


FIG. 13B

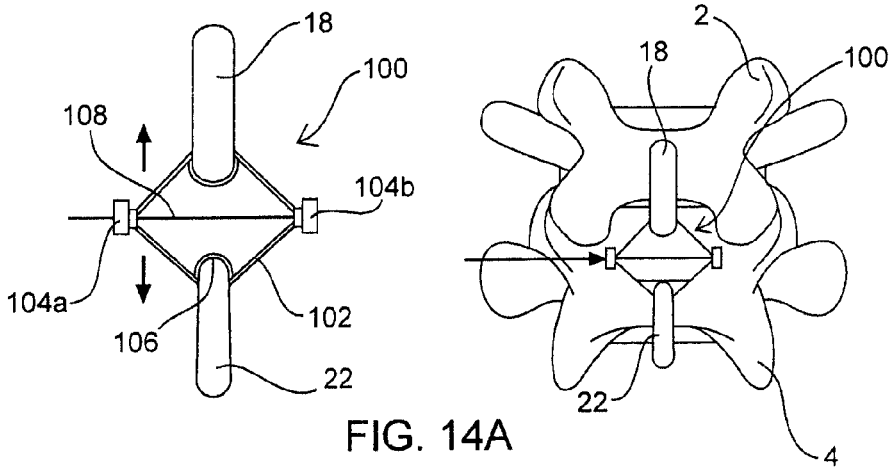


FIG. 14A

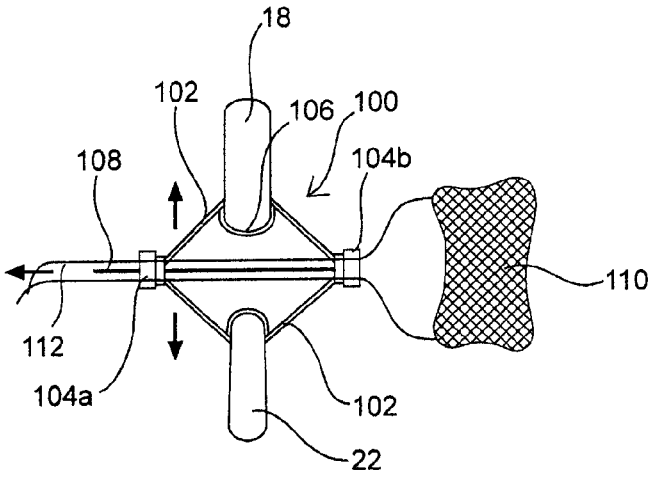


FIG. 14B

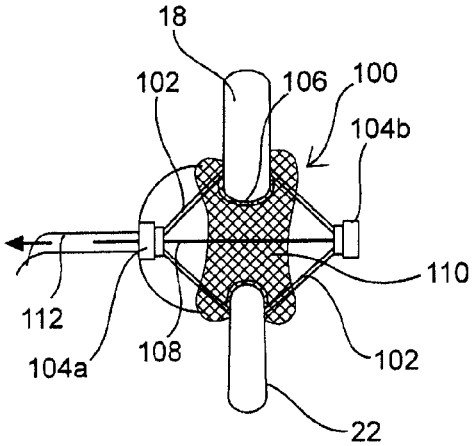


FIG. 14C

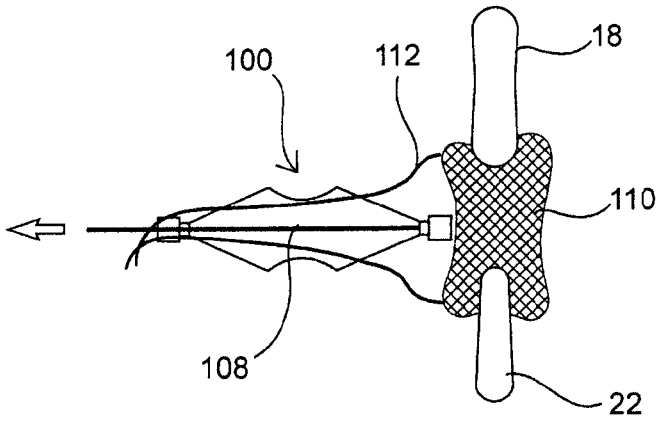


FIG. 14D

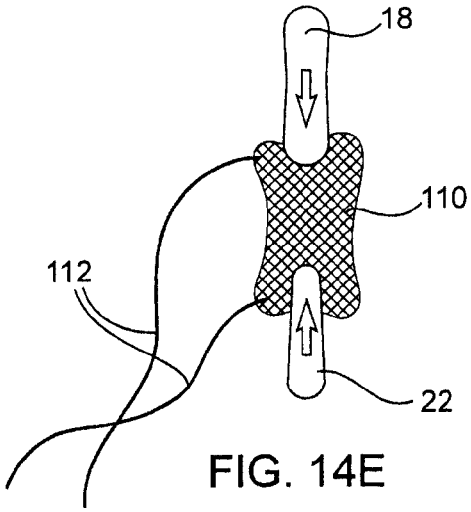


FIG. 14E

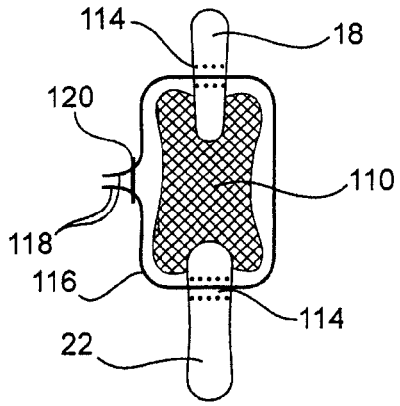


FIG. 14F

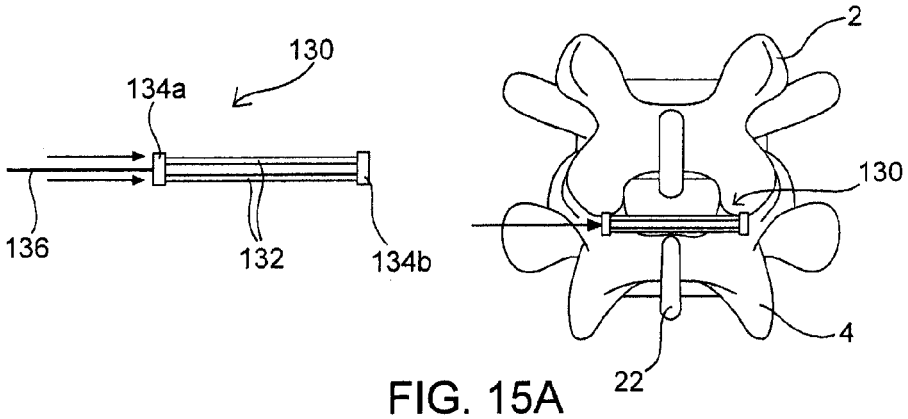


FIG. 15A

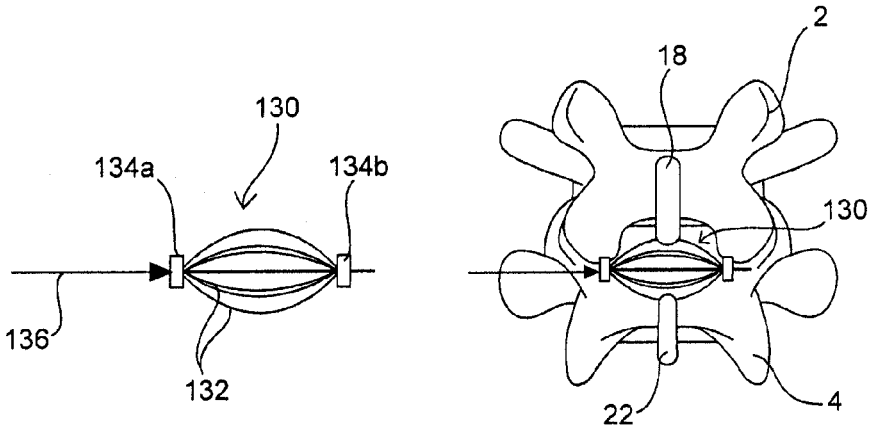


FIG. 15B

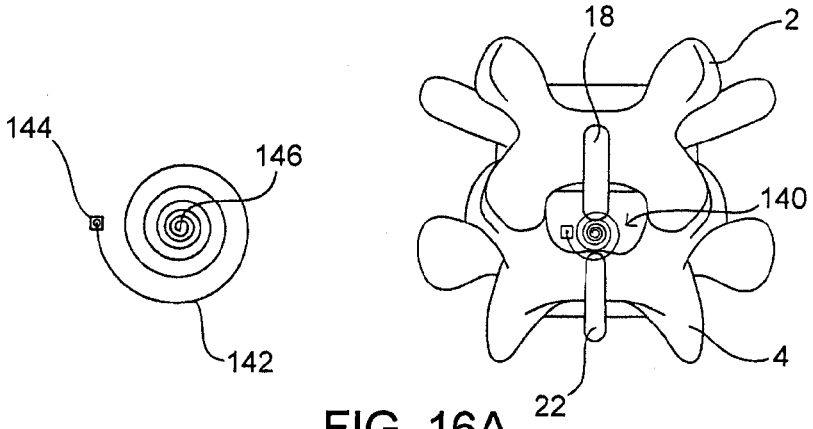


FIG. 16A

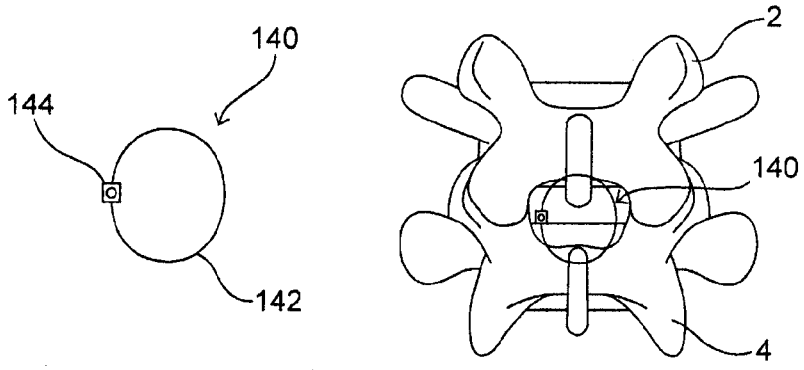


FIG. 16B

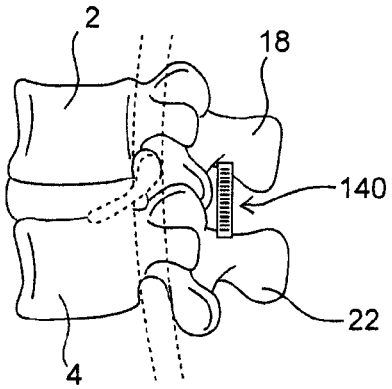


FIG. 16C

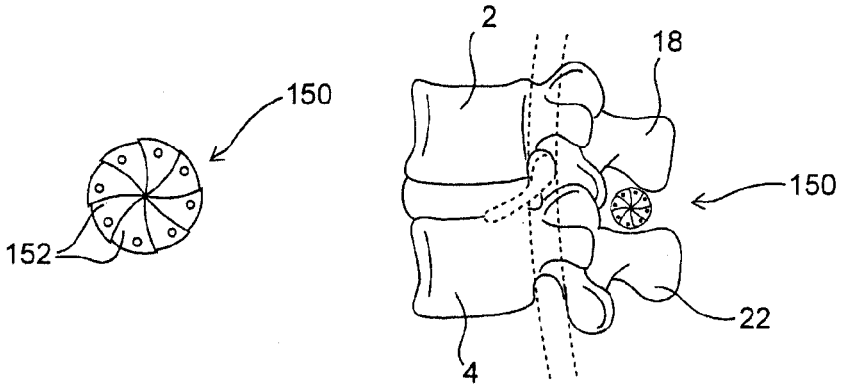


FIG. 17A

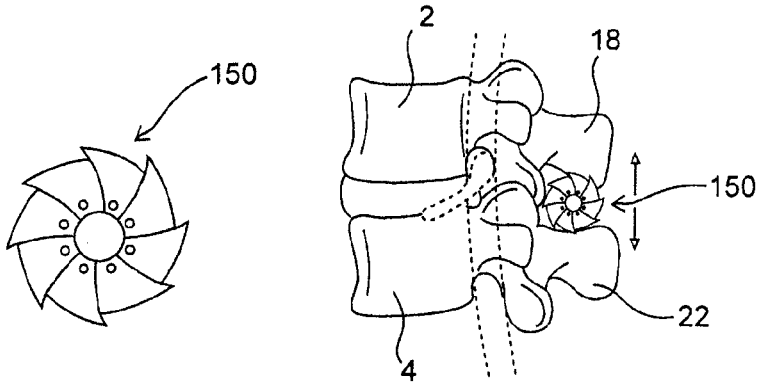


FIG. 17B

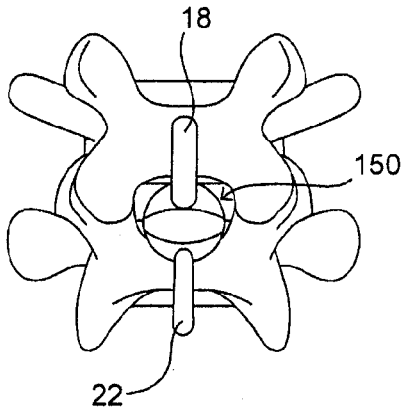


FIG. 17C

SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABILIZATION OF THE SPINE

CROSS-REFERENCE TO RELATED APPLICATIONS

The application is a divisional of U.S. patent application Ser. No. 11/006,502 filed Dec. 6, 2004, now U.S. Pat. No. 8,123,807, entitled "SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABALIZATION OF THE SPINE," which is a continuation-in-part of U.S. patent application Ser. No. 10/970,843, filed on Oct. 20, 2004, now U.S. Pat. No. 8,176,944, entitled "SYSTEMS AND METHODS FOR POSTERIOR DYNAMIC STABILIZATION OF THE SPINE," incorporated herein by reference.

FIELD OF THE INVENTION

The present invention is directed towards the treatment of spinal disorders and pain. More particularly, the present invention is directed to systems and methods of treating the spine, which eliminate pain and enable spinal motion, which effectively mimics that of a normally functioning spine.

BACKGROUND OF THE INVENTION

FIG. **1** illustrates a portion of the human spine having a superior vertebra **2** and an inferior vertebra **4**, with an intervertebral disc **6** located in between the two vertebral bodies. The superior vertebra **2** has superior facet joints **8***a* and **8***b*, inferior facet joints **10***a* and **10***b*, and spinous process **18**. Pedicles **3***a* and **3***b* interconnect the respective superior facet joints **8***a*, **8***b* to the vertebral body **2**. Extending laterally from superior facet joints **8***a*, **8***b* are transverse processes **7***a* and **7***b*, respectively. Extending between each inferior facet joints **10***a* and **10***b* and the spinous process **18** are laminal zones **5***a* and **5***b*, respectively. Similarly, inferior vertebra **4** has superior facet joints **12***a* and **12***b*, superior pedicles **9***a* and **9***b*, transverse processes **11***a* and **11***b*, inferior facet joints **14***a* and **14***b*, laminal zones **15***a* and **15***b*, and spinous process **22**.

The superior vertebra with its inferior facets, the inferior vertebra with its superior facet joints, the intervertebral disc, and seven spinal ligaments (not shown) extending between the superior and inferior vertebrae together comprise a spinal motion segment or functional spine unit. Each spinal motion segment enables motion along three orthogonal axes, both in rotation and in translation. The various spinal motions are illustrated in FIGS. **2**A-**2**C. In particular, FIG. **2**A illustrates flexion and extension motions and axial loading, FIG. **2**B illustrates lateral bending motion and FIG. **2**C illustrated axial rotational motion. A normally functioning spinal motion segment provides physiological limits and stiffness in each rotational and translational direction to create a stable and strong column structure to support physiological loads.

Traumatic, inflammatory, metabolic, synovial, neoplastic and degenerative disorders of the spine can produce debilitating pain that can affect a spinal motion segment's ability to properly function. The specific location or source of spinal pain is most often an affected intervertebral disc or facet joint. Often, a disorder in one location or spinal component can lead to eventual deterioration or disorder, and ultimately, pain in the other.

Spine fusion (arthrodesis) is a procedure in which two or more adjacent vertebral bodies are fused together. It is one of the most common approaches to alleviating various types of spinal pain, particularly pain associated with one or more affected intervertebral discs. While spine fusion generally

helps to eliminate certain types of pain, it has been shown to decrease function by limiting the range of motion for patients in flexion, extension, rotation and lateral bending. Furthermore, the fusion creates increased stresses on adjacent non-fused motion segments and accelerated degeneration of the motion segments. Additionally, pseudarthrosis (resulting from an incomplete or ineffective fusion) may not provide the expected pain-relief for the patient. Also, the device(s) used for fusion, whether artificial or biological, may migrate out of the fusion site creating significant new problems for the patient.

Various technologies and approaches have been developed to treat spinal pain without fusion in order to maintain or recreate the natural biomechanics of the spine. To this end, significant efforts are being made in the use of implantable artificial intervertebral discs. Artificial discs are intended to restore articulation between vertebral bodies so as to recreate the full range of motion normally allowed by the elastic properties of the natural disc. Unfortunately, the currently available artificial discs do not adequately address all of the mechanics of motion for the spinal column.

It has been found that the facet joints can also be a significant source of spinal disorders and debilitating pain. For example, a patient may suffer from arthritic facet joints, severe facet joint tropism, otherwise deformed facet joints, facet joint injuries, etc. These disorders lead to spinal stenosis, degenerative spondylolithesis, and/or isthmic spondylotlisthesis, pinching the nerves that extend between the affected vertebrae.

Current interventions for the treatment of facet joint disorders have not been found to provide completely successful results. Facetectomy (removal of the facet joints) may provide some pain relief; but as the facet joints help to support axial, torsional, and shear loads that act on the spinal column in addition to providing a sliding articulation and mechanism for load transmission, their removal inhibits natural spinal function. Laminectomy (removal of the lamina, including the spinal arch and the spinous process) may also provide pain relief associated with facet joint disorders; however, the spine is made less stable and subject to hypermobility. Problems with the facet joints can also complicate treatments associated with other portions of the spine. In fact, contraindications for disc replacement include arthritic facet joints, absent facet joints, severe facet joint tropism, or otherwise deformed facet joints due to the inability of the artificial disc (when used with compromised or missing facet joints) to properly restore the natural biomechanics of the spinal motion segment.

While various attempts have been made at facet joint replacement, they have been inadequate. This is due to the fact that prosthetic facet joints preserve existing bony structures and therefore do not address pathologies that affect facet joints themselves. Certain facet joint prostheses, such as those disclosed in U.S. Pat. No. 6,132,464, are intended to be supported on the lamina or the posterior arch. As the lamina is a very complex and highly variable anatomical structure, it is very difficult to design a prosthesis that provides reproducible positioning against the lamina to correctly locate the prosthetic facet joints. In addition, when facet joint replacement involves complete removal and replacement of the natural facet joint, as disclosed in U.S. Pat. No. 6,579,319, the prosthesis is unlikely to endure the loads and cycling experienced by the vertebra. Thus, the facet joint replacement may be subject to long-term displacement. Furthermore, when facet joint disorders are accompanied by disease or trauma to other structures of a vertebra (such as the lamina, spinous process, and/or transverse processes) facet joint replacement is insufficient to treat the problem(s).

Most recently, surgical-based technologies, referred to as "dynamic posterior stabilization," have been developed to address spinal pain resulting from more than one disorder, when more than one structure of the spine have been compromised. An objective of such technologies is to provide the support of fusion-based implants while maximizing the natural biomechanics of the spine. Dynamic posterior stabilization systems typically fall into one of two general categories: posterior pedicle screw-based systems and interspinous spacers.

Examples of pedicle screw-based systems are disclosed in U.S. Pat. Nos. 5,015,247, 5,484,437, 5,489,308, 5,609,636 and 5,658,337, 5,741,253, 6,080,155, 6,096,038, 6,264,656 and 6,270,498. These types of systems involve the use of screws that are positioned in the vertebral body through the pedicle. Certain types of these pedicle screw-based systems may be used to augment compromised facet joints, while others require removal of the spinous process and/or the facet joints for implantation. One such system, the Zimmer Spine Dynesys® employs a cord which is extended between the pedicle screws and a fairly rigid spacer which is passed over the cord and positioned between the screws. While this system is able to provide load sharing and restoration of disc height, because it is so rigid, it does not effective in preserving the natural motion of the spinal segment into which it is implanted. Other pedicle screw-based systems employ articulating joints between the pedicle screws. Because these types of systems require the use of pedicle screws, implantation of the systems are often more invasive to implant than interspinous spacers.

Where the level of disability or pain to the affected spinal motion segments is not that severe or where the condition, such as an injury, is not chronic, the use of interspinous spacers are preferred over pedicle based systems as they require a less invasive implantation approach and less dissection of the surrounding tissue and ligaments. Examples of interspinous spacers are disclosed in U.S. Pat. Nos. Re. 36,211, 5,645,599, 6,149,642, 6,500178, 6,695,842, 6,716,245 and 6,761,720. The spacers, which are made of either a hard or compliant material, are placed in between adjacent spinous processes. The harder material spacers are fixed in place by means of the opposing force caused by distracting the affected spinal segment and/or by use of keels or screws that anchor into the spinous process. While slightly less invasive than the procedures required for implanting a pedicle screw-based dynamic stabilization system, implantation of hard or solid interspinous spacers still requires dissection of muscle tissue and of the supraspinous and interspinous ligaments. Additionally, these tend to facilitate spinal motion that is less analogous to the natural spinal motion than do the more compliant and flexible interspinous spacers. Another advantage of the compliant/flexible interspinous spacers is the ability to deliver them somewhat less invasively than those that are not compliant or flexible; however, their compliancy makes them more susceptible to displacement or migration over time. To obviate this risk, many of these spacers employ straps or the like that are wrapped around the spinous processes of the vertebrae above and below the level where the spacer is implanted. Of course, this requires some additional tissue and ligament dissection superior and inferior to the implant site, i.e., at least within the adjacent interspinous spaces.

With the limitations of current spine stabilization technologies, there is clearly a need for an improved means and method for dynamic posterior stabilization of the spine that address the drawbacks of prior devices. In particular, it would be highly beneficial to have a dynamic stabilization system that involves a minimally invasive implantation procedure, where the extent of distraction between the affected vertebrae is adjustable upon implantation and at a later time if necessary. It would be additionally advantageous if the system or device was also removable in a minimally invasive manner.

SUMMARY OF THE INVENTION

The present invention provides devices, systems and methods for stabilizing at least one spinal motion segment. The devices include an expandable spacer or member having an unexpanded configuration and an expanded configuration, wherein the expandable member in an expanded configuration has a size, volume and/or shape configured for positioning between the spinous processes of adjacent vertebrae in order to distract the vertebrae relative to each other.

In certain embodiments, the expandable member is a balloon made of either non-compliant or compliant material which may be porous or non-porous, or may include a mesh material which may be coated or lined with a porous or non-porous material. The device may further include a port for coupling to a source of an inflation and/or expansion medium for inflating and/or expanding the expandable member. In certain embodiments, the port may be used to deflate or evacuate the expandable member. The devices may further include one or more tabs for anchoring the expandable member to the spinous processes. Optionally, the device may include one marker on a surface of the expandable member to facilitate fluoroscopic imaging.

In other embodiments, the expandable members are cages, struts, wires or solid objects having annular, spherical or elliptical shapes when in an expanded condition. The expandable members may be self-expanding or adjustably expandable depending on the extent of distraction required.

The invention further includes systems for stabilizing at least one spinal motion segment which include one or more expandable members and an expansion medium for injection within or for filling the interior of the expandable member via the port. The subject systems may further include at least one means for anchoring or securing the expandable member to the spinal motion segment.

The invention further includes methods for stabilizing at least one spinal motion segment which involve the implantation of one or more devices or expandable spacers of the present invention, in which the expandable member is positioned between the spinous processes of adjacent vertebrae in an unexpanded condition and then subsequently expanded to a size and/or shape for selectively distracting the adjacent vertebrae. The invention also contemplates the temporary implantation of the subject devices which may be subsequently removed from the patient once the intended treatment is complete. Many of the methods involve the percutaneous implantation of the subject devices.

These and other objects, advantages, and features of the invention will become apparent to those persons skilled in the art upon reading the details of the invention as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to-scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

FIG. **1** illustrated s perspective view of a portion of the human spine having two vertebral segments.

FIGS. **2**A, **2**B and **2**C illustrate left side, dorsal and top views, respectively, of the spinal segments of FIG. **1**A under going various motions.

FIG. **3**A illustrates an interspinous device of the present invention in an unexpanded or collapsed state coupled to a cannula of the delivery system of the present invention. FIG. **3**B is an enlarged view of the interspinous device of FIG. **3**A.

FIG. **4**A illustrates an interspinous device of the present invention in an expanded state coupled to a cannula of the delivery system of the present invention. FIG. **4**B is an enlarged view of the interspinous device of FIG. **4**A.

FIGS. **5**A-**5**C illustrates top, dorsal and side views of an initial step of the method of the present invention in which a cannula is delivered to the target implant site.

FIGS. **6**A and **6**B illustrate dorsal and side views of the step of dissecting an opening within the spinous ligament utilizing a cutting instrument of the system of FIGS. **3** and **4**. FIG. **6**C is an enlarged view of the target area within the spinous ligament.

FIGS. **7**A and **7**B illustrate dorsal aid side views of the step of inserting the interspinous device of FIG. **4**A into the dissected opening of the spinous ligament. FIGS. **7**C and **7**D are enlarged views of the target area in FIGS. **7**A and **7**B, respectively.

FIGS. **8**A and **8**B illustrate dorsal aid side views of the step of inflating or expanding the interspinous device of FIG. **4**A within the implant site. FIGS. **8**C and **8**D are enlarged views of the target area in FIGS. **8**C and **8**D, respectively.

FIG. **9**A illustrates a side view of the step of filling the interspinous device of FIG. **4**A with an expansion medium. FIG. **9**B is an enlarged view of the target area in FIG. **9**A.

FIG. **10**A illustrates a dorsal view of the step of further securing the interspinous device of FIG. **4**A within the implant site. FIG. **10**B is an enlarged view of the target area in FIG. **10**A.

FIGS. **11**A and **11**B illustrate dorsal aid side views of the step of inserting another embodiment of an interspinous device into the dissected opening of the spinous ligament. FIGS. **11**C and **11**D are enlarged views of the target area in FIGS. **11**A and **11**B, respectively.

FIGS. **12**A and **12**B illustrate dorsal aid side views of the step of expanding the interspinous device of FIGS. **11**A-**11**D within the implant site. FIGS. **12**C and **12**D are enlarged views of the target area in FIGS. **12**A and **12**B, respectively.

FIG. **13**A illustrates a side view of the step of filling the interspinous device of FIGS. **11**A-**11**D with an expansion medium. FIG. **13**B is an enlarged view of the target area in FIG. **13**A.

FIGS. **14**A-**14**F illustrate dorsal views of another interspinous device of the present invention and a device for implanting the interspinous device where the implantation device is used initially district the interspinous space prior to implanting the interspinous device.

FIGS. **15**A and **15**B illustrate dorsal views of another interspinous device of the present invention implanted within an interspinous space.

FIGS. **16**A and **16**B illustrate dorsal views of another interspinous device of the present invention implanted within an interspinous space. FIG. **16**C is a side view of FIG. **16**B.

FIGS. **17**A and **17**B illustrate side views of another interspinous device of the present invention implanted within an interspinous space. FIG. **17**C is a dorsal view of FIG. **17**B.

DETAILED DESCRIPTION OF THE INVENTION

Before the subject devices, systems and methods are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a spinal segment" may include a plurality of such spinal segments and reference to "the screw" includes reference to one or more screw and equivalents thereof known to those skilled in the art, and so forth.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

The present invention will now be described in greater detail by way of the following description of exemplary embodiments and variations of the devices and methods of the present invention. The invention generally includes an interspinous spacer device as well as instruments for the percutaneous implantation of the interspinous spacer. A key feature of the interspinous spacer device is that it is expandable from a low profile configuration to a higher profile or operative configuration. This design allows the device, when in the low profile condition, to be delivered by percutaneous means without requiring the removal of any portion of the spinal motion segment into which the device is implanted.

Referring now to the drawings and to FIGS. **3** and **4** in particular, an exemplary interspinous spacer device **24** of the present invention is illustrated in collapsed and expanded configurations, respectively. Interspinous device **24** includes an expandable spacer body **4** that has a size and shape when in the expanded condition for operative positioning between the spinous processes of adjacent superior and inferior vertebrae of the spinal motion segment being treated. Expandable body **34** is made of an expandable or inflatable biocompatible material such as non-porous material, e.g., latex, acrylate or a metal mesh, e.g., a nitinol or titanium cage.

Those spacers made of an inflatable non-porous material, i.e., balloon type spacers (see FIGS. **3**-**10**), are inflated with

an inflation or expansion medium, such as air, saline, another biologically compatible fluid, or a flowable solid material, such as polyurethane, or a gel, which thickens or hardens substantially upon injection into balloon **34**. In one embodiment, balloon **34** is initially inflated with air to provide some structure or rigidity to it to facilitate its optimum positioning and alignment between the spinous processes. Once positioned as desired, balloon **34** is injected with a flowable solid material (the air therein being displaced possibly via a vent hole within port **32**). In certain embodiments, the expandable body is made of a non-compliant or semi-compliant material so as to maintain a substantially fixed shape or configuration and ensure proper, long-term retention within the implant site. In other embodiments, the expandable member may be made of a compliant material. In any embodiment, the compressibility and flexibility of balloon **34** can be selected to address the indications being treated.

Other embodiments of the subject spacers are made of an expandable mesh or cage (see FIGS. **11-12**). The mesh or cage maybe made of a super-elastic memory material which is compressible for delivery through a cannula and which is self-expanding upon implantation. Upon expansion, the mesh or cage may be self-retaining whereby its struts, links or wires are sufficiently rigid by themselves to maintain the expanded condition and withstand the natural forces exerted on it by spine. The mesh or cage may have an exterior coating or an interior lining made of materials similar to or the same as that used for the balloon spacers, or may otherwise be embedded in such material. In certain embodiments, an expansion medium may be used to fill the interior of the cage or mesh structure, such as with a biologically compatible fluid or flowable solid material used with the balloon-type embodiments.

In certain embodiments of present invention, either during the implant procedure or in a subsequent procedure, the size or volume of the implanted expandable spacer may be selectively adjusted or varied. For example, after an initial assessment upon implant, it may be necessary to adjust, either reduce or increase, the size or volume of the spacer to optimize the intended treatment. Further, it may be intended to only temporarily implant the spacer for the purpose of treating a temporary condition, e.g., an injured or bulging or herniated disk. Once the repair is achieved or the treatment completed, the spacer may be removed, either with or without substantially reducing the size or volume of the spacer. In other embodiments, the spacer as well as the inflation/expansion material may be made of biodegradable materials wherein the spacer degrades after a time in which the injury is healed or the treatment completed.

When unexpanded or deflated, as shown in FIGS. **3**A and **3**B (balloon type) and in FIGS. **11**C and **11**D (mesh type) expandable body **34** has a low profile, such as a narrow, elongated shape, to be easily translated through a delivery cannula **70**. The shape of expandable body **34**, when in an expanded or inflated state, has larger profile which is generally H-shaped. Expandable body **34** has lateral or side portions **30**, end portions **26** and apexes **28** defined between the side portions **30** and the end portions **26**. End portions **26** are preferably recessed or contoured to provide a narrowed central portion along the height dimension or major axis of expandable body **34** to readily fit between and to conform to the spinous processes. Accordingly, expandable body **34** has an apex-to-apex dimension (i.e., height or major axis dimension) from about 3 to about 5 cm and a width dimension (minor axis dimension) from about 2 to about 4 cm

For those embodiments of expandable bodies which comprise a balloon configuration, balloon **34** has an inflation or injection port **32** at a sidewall **30** for coupling to a source of inflation or expansion material or medium. Port **32** may consist of a one-way valve which is self-sealing upon release from an inflation mechanism or tube **76**. Port **32** is further configured to releasably engage from tube **76**, where such engagement may be threaded or involve a releasable locking mechanism. Where the expandable body comprises a mesh or cage, port **32** simply acts as an exit port, however, where an expansion material is used, it also functions as an injection port for the expansion material.

Optionally, device **24** may include a pair of tabs **36** which may be positioned on one side of the device where the tabs **36** are preferably situated at the apexes **28** of expandable body **34**. Pins or screws (not yet shown) may be used to secure the tabs against the spinous process to further ensure long-term retention of device **24** within the implant site. Tabs **36** are made of a biocompatible material, such as latex, acrylate, rubber, or a metal, and may be made of the same material used for the expandable member **34**. Shown here attached to tabs **36** are tethers **38** which are used in part to manipulate the positioning of expandable body **34** upon implantation into the targeted spinal motion segment. The tethers may be made of any suitable material including but not limited to materials used to make conventional sutures. They may also be made of a biodegradable material. While two tabs and associated tethers are provided in the illustrated embodiment, one, three or more may be employed, where the respective tabs are located on the expandable body so as to be adjacent a bony structure of the vertebra suitable for anchoring thereto. In embodiments which do not employ securing tabs **36**, tethers **38** may be attached directly to the expandable body itself.

Optionally still, device **24** may further include radiopaque markers **40** on the surface of expandable body **34** visible under fluoroscopic imaging to facilitate positioning of the expandable body. Any number of markers **40** may be employed anywhere on expandable body **34**, however, as few as four markers, one at each apex, may be sufficient. With embodiments employing cage or mesh expandable bodies, the cage or mesh material itself may be radiopaque.

A system of the present invention includes a cannula device **70** having an outer sheath **72**, a proximal hub **78** and preferably at least two interior lumens **74**, **76** for the percutaneous delivery the device and other tools for implanting the device, which tools may include a cutting instrument **62** (see FIG. **6**C), a device delivery instrument **76**, an endoscope, etc., which tools will be further discussed in the context of the description of the subject methods with reference to FIGS. **5-10**.

In FIGS. **5**A-**5**C, the spinal motion segment of FIG. **1** is illustrated having spinal ligament **54** extending between the superior spinous process **18** and the inferior spinous process **22**. A percutaneous puncture is made into the skin **30** adjacent the target spinal motion segment of a patient undergoing the implantation of the interspinous device of the present invention, and a cannula **70** is penetrated to the spinous ligament **54**. The puncture and subsequent penetration may be made by way of a sharp distal tip of cannula **70** or by a trocar (not shown) delivered through a lumen of cannula **70**.

As illustrated in FIGS. **6**A-**6**C, the spinous ligament **54** is then dissected and an opening **58** created therein by way of a cutting instrument **60**, such as a simple scalpel, an electrosurgical device or the like, delivered through a lumen of cannula **70**. Cutting instrument **60** may then be removed from cannula **70** and, as illustrated in FIGS. **7**A-**7**D (balloon type) and in FIGS. **11**A-**11**D (cage type), a delivery instrument **16** having interspinous device **24** operatively preloaded is delivered through cannula **70**.

The preloading of device **24** to delivery instrument **76** involves providing expandable body **34** in an unexpanded or deflated state and releasably coupled, as described above, by way of inflation or injection port **32** of expandable body **34** to the distal end of delivery instrument **76**. In addition to functioning as a pusher, instrument **76** may act as an inflation lumen for balloon type embodiments through which an inflation medium is transported to within expandable body **34**.

Depending upon the material used to fabricate expandable body **34**, the expandable body may have a degree of stiffness in an unexpanded or deflated state such that it may maintain an elongated configuration so as to be directly insertable and pushable through cannula **70**. This may the case where the expandable member **34** is made of a cage or mesh material. Alternatively, a pusher or small diameter rod (not shown) may be inserted through inflation port **32** to within expandable body **34** to keep it in an elongated state so as to prevent expandable body **4** from bunching within cannula **70** and to provide some rigidity to more effectively position the expandable body in the target implant site. The rod is then removed from expandable body **34** and from delivery device **76** upon positioning the expandable body at the target implant site. In either case, expandable body **34** is folded or compressed about its minor axis with the side wall opposite the inflation port **32** defining a distal end **25** (see FIG. **3**B) and the apexes **28** of the expandable body folded proximally of distal end **25** to provide a streamline, low profile configuration for delivery through cannula **70**.

Once interspinous device **24** is preloaded to delivery device **76** as just described, device **24** is then inserted into a lumen of cannula **70** with tethers **38** pulled back and trail proximally so that the tether ends **38***a* extend from hub **78** of cannula **70**. Expandable body member **34** is translated through cannula **70** to within opening **58** within spinous ligament **54** as best illustrated in FIGS. **7**C and **11**C. For best results, expandable body **34** is centrally positioned within opening **58** so that the countered ends **26** of expandable body **34** readily engage with the opposed spinous processes **18**, **22**. Fluoroscopy may be employed to visualize markers **40** so as to ensure that expandable body **34** centrally straddles the spinous ligament opening **58**, i.e., the markers on the distal side **25** of the expandable body are positioned on one side of the spine and the markers on the proximal side of the expandable body (the side on which port **32** is located) are positioned on the other side of the spine.

Once centrally positioned, expandable body **34** is inflated or expanded, as illustrated in FIGS. **8**A-**8**D and **12**A-**12**D. For balloon spacers, inflation occurs by allowing an inflation or expansion medium, as discussed above, to enter into the interior of the expandable body via port **32**. For expandable mesh spacers, the expandable body may be configured to expand automatically upon exiting cannula **70**. The inflation or expansion of expandable body **34** may also be visualized under fluoroscopy whereby markers **40**, as best shown in FIG. **8**C, are observed and the position of expandable body **34** may be adjusted to ensure optimum positioning upon complete inflation. Adjustments of the expandable body's position may be accomplished by manually pulling on one or both tether ends **38***a* which in turn pulls on tabs **26** to which the tethers **38** are attached at their proximal ends. The tethers **38** are selectively pulled as necessary to center or optimally position interspinous expandable body **34** to achieve the desired treatment of the targeted spinal motion segment.

With embodiments in which the expandable body is initially inflated with air and then filled with a solid or fluid medium, the latter is preferably not delivered or injected into the interior of the expandable body until the position of the expandable body within the interspinous space has been verified and optimized. This is beneficial in situations where, upon inflation, it is found that the expandable body is misaligned within the interspinous space and requires repositioning. The expandable body may simply be deflated of air to the extent necessary and repositioned in a less inflated or deflated state. If necessary, for example where it is found that the maximum spacer or expandable body size is insufficient for the particular application at hand, expandable body **34** may be completely deflated and removed and replaced with a more suitably sized unit.

For balloon spacers and those mesh spacers which are not by themselves sufficiently self-retaining, once the position and extent of inflation or expansion of expandable body **34** are optimized, the expansion medium, e.g., polyurethane, is allowed to flow or injected into the interior of the expandable body via port **32**. As illustrated in FIGS. **9**A and **9**B, expandable body **34** is caused to expand to a selected volume and in so doing forces apart (see arrow **80**) the spinous processes **18**, **22** in between which it is situated. This selective distraction of the spinous processes also results in distraction of the vertebral bodies **2**, **4** (see arrow **82**) which in turn allows the disk, if bulging or distended, to retract to a more natural position (see arrow **84**). Again, the extent of distraction or lordosis undergone by the subject vertebrae can be monitored by observing expandable body markers **40** under fluoroscopy.

The extent of possible distraction maybe limited by the capacity of expandable body **34** and the type of expandable body material employed. In certain embodiments, such as expandable bodies made of non-compliant or semi-compliant balloons, the requisite volume of the inflation medium may be substantially fixed whereby the balloon achieves its fully expanded configuration upon filling it with the fixed volume of medium. In other embodiments, such as with balloons made of a compliant material, the extent of expansion may be variable and selectable intraoperatively depending on the extent of lordosis or distraction to be achieved between the spinous processes in which balloon **34** is now interposed.

Upon achieving the desired distraction between the vertebrae, inflation/expansion lumen **76** is disengaged from expandable body port **32** which then becomes sealed by means of a one-way valve that is closed upon disengagement of lumen **76**. Inflation/expansion lumen is then removed from cannula **70**. While the opposing compressive force exerted on expandable body **34** by the distracted spinous processes **18**, **22** may be sufficient to permanently retain expandable body **34** therebetween, the interspinous device may be further secured to the spinous processes **18**, **22** to ensure that the expandable body does not slip or migrate from its implanted position. To this end, tabs **36** are anchored to the spinous processes as illustrated in FIGS. **10**A and **10**B and in FIGS. **13**A and **13**B. Any type of anchoring means, such as screws, tacks, staples, adhesive, etc. may be employed to anchor tabs **36**. Here, cannulated screws **90** are used as anchors and are delivered to the target site releasably coupled to screw driving instrument **88**. While various screw attachment and release mechanisms may be employed, a simple configuration involves providing the screws **90** with a threaded inner lumen which is threadably engagable with the threaded distal end of instrument **88**.

To ensure accurate placement of screws **90**, along with instrument **88**, can be tracked and translated over respective tethers **38**, which function as guide wires. By manipulating instrument **88**, the screws are driven or screwed into the respective spinous process. Screwdriver **88** is then disengaged or unscrewed from screw **90**. After both tabs **36** are

securely anchored to the spinous processes, the screwdriver and the cannula may be removed from the patient's back.

FIGS. **14**A-**14**F illustrate an alternative method for implanting the expandable member. In particular, the method contemplates pre-inflating or pre-expanding the expandable member prior to positioning the expandable member within the interspinous space. To accomplish this, the vertebrae **2** and **4** may be distracted prior to insertion of the pre-expandable balloon implant. A temporary distraction mechanism, such as another balloon or a mechanically actuated device, is inserted into the interspinous space. When the desired amount of distraction is achieved, the permanent or implantable expandable member can then be placed within the interspinous space, and the temporary distraction member may then be removed from the space.

While certain of the expandable spacers are intended to be permanently implanted within a spine, certain others may be implanted only temporarily to facilitate the healing of an injury or the treatment of a reversible or non-chronic condition, such as a herniated disk. For such temporary treatments, the expansion material most likely is a fluid, such as saline, which may be easily aspirated through port **32** or may be allowed to drain out via a penetration or cut made in the expandable member. In those embodiments in which the expansion material is a flowable solid, which may or may not subsequently harden within the expandable member, the material may be one that is reconstitutable into a liquid form which may then be subsequently aspirated or evacuated from the expandable member. For percutaneous removal of the expandable member, a cannula such as cannula **70** may be used and an aspiration instrument delivered therethrough and coupled to port **32**. After deflation and/or evacuation of the expandable member, and removal of the tacks, sutures, staples, etc. if such are used to secure tabs **36**, the expandable member may be easily removed through cannula **70**. With biodegradable spacers, removal of the spacer is obviated.

It should be noted that any of the above-described steps or procedures, including but not limited to cannulation of the target area, dissection of the spinous ligament, insertion of the expandable body within the dissected opening of the spinous ligament, inflation and/or expansion of the expandable body, adjustment or readjustment of the expandable body, and anchoring of the tabs, etc., may be facilitated by way of a scope **62** delivered through a lumen of cannula **70** to the open distal tip of cannula **70**. Alternatively, a second cannula delivered through another percutaneous penetration may be employed for use of an endoscope and any other instruments needed to facilitate the procedure.

FIG. **14**A illustrates an exemplary embodiment of a temporary distraction mechanism **100** having an expandable strut configuration. Mechanism **100** includes bilateral struts **102** which are hinged and foldable at hubs **104**, respectively. Bridging the struts **102** at superior and inferior ends are spinous process engagement portions **106** which are preferably configured to conformingly engage with the spinous processes **18**, **22**. Extending centrally between hubs **104** is a distal portion of guide wire **108**, which also extends proximally through proximal hub **104***a*. Guide wire **108** is in threaded engagement with both hub **104***a* whereby hub **104***a* can be translated both proximally and distally along guide wire **108**. As such, expandable member **100** can be provided in a low-profile, compressed state upon proximally translating hub **104***a* in a proximal direction. In such a low-profile state, distraction mechanism **100** is easily deliverable through cannula **70**, as described above, to with the interspinous space. Upon proper positioning, distraction mechanism **100** is expandable to a higher profile or expanded state by translating hub **104***a* toward hub **104***b* in a distal direction along guide wire **108**, as illustrated in FIG. **14**A.

After the desired amount of distraction is achieved between vertebrae **2** and **4**, an implantable expandable member **110** of the present invention is delivered adjacent the distracted spinal motion segment. Expandable member **110** may be delivered from the same incision and side as distraction mechanism **100** (ipsolateral approach) and as well as through the same working channel, or may be delivered through a different incision on the same or opposing side of the spinal motion segment being treated (bilateral approach) using two different working channels. In the illustrated embodiment, expandable member **110** is delivered from the same side of the spinous process as distraction mechanism **100**. Expandable member **110** may delivered through a separate designated lumen in cannula **70** and translated distally of hub **104***b* of distraction mechanism **100**.

As shown in FIG. **14**B, after deployment, expandable member **110** is inflated or expanded as described above with respect to expandable member **34**, for example, by way of an inflation lumen extending through guide wire **108**. Tethers **112** may be provided on expandable member **110** to retract and manipulate it to within the interspinous space, as illustrated in FIG. **14**C. Once expandable member **110** is properly positioned within the interspinous space, distraction mechanism **100** may be removed from the interspinous space immediately or, if the expandable member has been filled with a curable expansion medium or one that involves setting or hardening, the distraction mechanism may be kept in the interspinous space until the desired consistency, curing or hardening has been achieved by the expansion medium. To remove distraction mechanism **100** from the interspinous space, its profile is reduced to a low profile state, as illustrated in FIG. **14**D. As mentioned earlier, this is accomplished by translating proximal hub **104***a* proximally along guide wire **108**. Distraction member **100** may be retracted out through a cannula or removed directly in this low profile state, leaving expandable member **100** alone within the implant site as illustrated in FIG. **14**E. Tethers **112** may then be cut or secured in place. Optionally, a strap **116** or the like may be implanted to further secure expandable member **110** within the implant site and reduce the risk of migration. Here, bores or holes **114** have been formed through the thickness of the spinous processes **18**, **22** and strap **116** threaded there through with its ends secured together by a securing means **120**, such as a suture, staple or clip, as illustrated in FIG. **14**F. Alternatively, strap **116** could be wrapped around the spinous processes **18**, **22**.

In addition to the expandable balloon spacers, the present invention further provides for mechanically expandable spacers such as those illustrated in FIGS. **15-17**. For example, expandable spacer **130** of FIG. **15**A is a cage-like structure having spaced-apart, parallel strut members **132** extending between and fixed to hubs **134**. Like the distraction mechanism of FIGS. **14**A-**14**F, spacer **130** may be provided on and deliverable by way of a guide wire **136** which is threadably engaged to and disengagable from proximal hub **134***a*. After placement of spacer **130** within the interspinous space, as illustrated in FIG. **15**A, spacer **130** is expanded by advancing proximal hub **134***a* distally along guide wire **136** thereby forcing struts **132** radially outward and away from each other whereby the expanded configuration of spacer **130** is elliptical or, in a more advanced state of expansion, substantially spherical. Once the desired degree of distraction is achieved between vertebrae **2** and **4**, guide wire **136** unthreaded from hub **134***a* and removed from the implant region.

FIGS. **16**A and **16**B illustrate another embodiment of an expandable spacer **140** which is in the form of a coiled band **142** terminating at an outer end **144** having a configuration for receiving and locking onto inner end **146** upon full expansion or unwinding of the coil. The diameter of coil **142** in an unexpanded or fully wound state is small enough to allow easy insertion between spinous processes **18**, **22**. Upon proper positioning within the interspinous space, coil **142** is allowed to expand and unwind thereby distracting vertebrae **2** and **4** apart from each other. Once the desire level of distraction is achieved, inner end **146** is coupled to outer end **144**. While the figures show band **142** inserted transversely to spinous processes **18**, **22**, it may alternatively be inserted in line or in the same plan defined by the spinous processes.

FIGS. **17**A-**17**C illustrate another interspinous spacer **150** having interlocked nested portions **152**. Nested portions **152** are each shaped and configured to be received within one of its adjacent portions and to receive the other of the adjacent portions when in a low profile state, as illustrated in FIG. **17**A. Upon expansion of spacer **150**, which may be spring loaded or be expandable by way of an instrument (not shown) which may be inserted into the spacer's center and rotated to flare portions **152**, vertebrae **2** and **4** are caused to distract from each other. Portions **152** may have a configuration or shape which allow them to bite or dig into the spinous process **18**, **22** and become securely retained therein.

The subject devices and systems may be provided in the form of a kit which includes at least one interspinous device of the present invention. A plurality of such devices may be provided where the devices have the same or varying sizes and shapes and are made of the same or varying materials. The kits may further include instruments and tools for implanting the subject devices, including but not limited to, a cannula, a trocar, a scope, a device delivery/inflation/expansion lumen, a cutting instrument, a screw driver, etc., as well as a selection of screws or other devices for anchoring the spacer tabs to the spinous processes. The kits may also include a supply of the expandable body inflation and/or expansion medium. Instructions for implanting the interspinous spacers and using the above-described instrumentation may also be provided with the kits.

The preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

That which is claimed is:

1. An interspinous device for stabilizing at least one spinal motion segment of a subject comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the device comprising:

an expandable member having an unexpanded configuration and an expanded configuration, wherein the expandable member in the unexpanded configuration has a size configured for delivery through a cannula and positioning between the first and second spinous process and in the expanded configuration provides distraction of the first and second spinous processes, wherein the expandable member includes

a first concave engagement portion,

a second concave engagement portion,

a hub,

at least one strut rotatably coupled to the hub, and

a central element positioned between the first and second concave engagement portions, wherein the central element is axially movable relative to the hub to cause the at least one strut to rotate relative to the hub to move the first and second concave engagement portions outwardly while the hub and the at least one strut are positioned with the subject and positioned directly posterior to the subject's spinal motion segment and also while the central element is positioned directly between the first and second spinous processes to mechanically actuate the expandable member from the unexpanded configuration to the expanded configuration such that the first spinous process is held by the first concave engagement portion and the second spinous process is held by the second concave engagement portion.

2. The device of claim **1**, wherein the at least one strut comprises a plurality of struts.

3. The device of claim **2**, wherein the hub is a first hub and the interspinous device further includes a second hub, wherein the at least one strut includes struts affixed between the first and second hubs, wherein the first and second hubs are spaced apart a sufficiently small distance such that the first and second hubs are positionable on opposite sides of a sagittal plane defined by the spinal motion segment and within the subject when the first spinous process is held by the first concave engagement portion and the second spinous process is held by the second concave engagement portion.

4. A kit for stabilizing at least one spinal motion segment comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the kit comprising:

the interspinous device of claim **1**; and

a cannula configured for percutaneous delivery to a target site within the spinal motion segment wherein the expandable member is deliverable through the cannula when in an unexpanded configuration.

5. The kit of claim **4**, further comprising instructions for implanting the expandable member between the first and second spinous processes.

6. The device of claim **1**, further comprising an expandable inflatable member positionable within the expandable member.

7. The device of claim **1** wherein the expandable member includes an inflatable member.

8. The device of claim **1**, wherein the expandable member is configured to move in a first direction through the cannula and into the position between the first and second spinous processes, wherein the first concave engagement portion and

the second concave engagement portion move away from each other in a second direction that is different from the first direction.

9. The device of claim **1**, wherein the first and second concave engagement portions move away from a longitudinal axis of the expandable member when the expandable member moves from the unexpanded configuration to the expanded configuration.

10. The device of claim **1** wherein the first and second concave engagement portions move in opposite directions when the central element moves axially along the expandable member.

11. The device of claim **1** wherein the first and second concave engagement portions move laterally outwardly past a distal end of a cannula device for delivering the interspinous device when the expandable member is moved from the unexpanded configuration to the expanded configuration and is connected to the cannula device.

12. The device of claim **1** wherein the expandable member is configured to move from the expanded configuration to the unexpanded configuration while a cannula device is mechanically coupled to the expandable member.

13. The device of claim **1** wherein concave surfaces of the first and second concave engagement portions are positioned to contact and surround at least portions of the first and second spinous processes.

14. A system for stabilizing at least one spinal motion segment of a subject comprising a first vertebra having a first spinous process and a second vertebra having a second spinous process, the system comprising:

an expandable member including a first concave engagement portion, a second concave engagement portion, and rotatable members, wherein the rotatable members are rotatable about axes of rotation to move the first and second concave engagement portions such that the expandable member moves between an unexpanded configuration and an expanded configuration while each of the rotatable members are positioned within the subject and the rotatable members are located directly posterior to the spinal motion segment, wherein the expandable member in the unexpanded configuration has a size configured for delivery through a cannula and positioning between the first and second spinous process and in the expanded configuration provides distraction of the first and second spinous processes held within the first and second concave engagement portions, respectively, wherein the expandable member is mechanically actuatable from the unexpanded configuration to the expanded configuration; and

means for mechanically actuating the expandable member to move the first and second concave engagement portions toward the first and second spinous processes, respectively, while the means for mechanically actuating is positioned directly between the first and second spinous processes and movable axially along the expandable member.

15. The system of claim **14**, wherein said mechanical actuation means is a guide wire.

16. The system of claim **14**, wherein the first and second concave engagement portions move away from a longitudinal axis of the expandable member when the expandable member moves from the unexpanded configuration to the expanded configuration.

17. An interspinous system, comprising:

an implant assembly that is mechanically actuatable between a first unexpanded configuration and a first expanded configuration, wherein the implant assembly includes

an expandable device having a first concave engagement portion, a second concave engagement portion, and strut, and

a drive element axially movable along the expandable device to rotate the sruts so as to move the first and second concave engagement portions away from one another, wherein the implant assembly in the first unexpanded configuration is deliverable through a cannula and positionable between a first and second spinous process of a subject's spine such that the first and second concave engagement portions and the drive member are positioned directly between the first and second spinous processes, and wherein when the implant assembly is in the first expanded configuration, the first and second concave engagement portions hold the first and second spinous processes, respectively, to provide distraction of the first and second spinous processes while the entire expandable device is positioned within the subject and positioned directly posterior to the subject's spine.

18. The interspinous system of claim **17**, wherein the expandable device is a first expandable device, and wherein the implant assembly further comprises:

a second expandable device that is inflatable between a second unexpanded configuration and a second expanded configuration.

19. The interspinous system of claim **18** wherein the second expandable device in the second unexpended configuration is positionable within the expandable device.

20. The interspinous system of claim **17**, wherein the implant assembly has an elongated shape for delivery through an lumen of the cannula.

21. The interspinous system of claim **17**, further comprising:

an implantable inflatable device inflatable between a second unexpanded configuration and a second expanded configuration such that the implantable inflatable device holds the first and second spinous processes while the implant assembly is collapsed and removed from the subject.

22. The interspinous system of claim **17** wherein concave surfaces of the first and second concave engagement portions are positioned to contact the first and second spinous processes.

23. An interspinous apparatus for distracting a first vertebra of a subject having a first spinous process and a second vertebra of the subject having a second spinous process, the interspinous apparatus comprising:

an implant assembly including a first concave engagement portion, a second concave engagement portion, a hub, at least one rotatable member, and a drive member, wherein the implant assembly has an unexpanded configuration and an expanded configuration, wherein the implant assembly in the unexpanded configuration is sized for delivery to a position between the first and second spinous processes such that the first and second concave engagement portions and the drive member are positioned directly between the first and second spinous processes, wherein the implant assembly is mechanically actuated from the unexpanded configuration to the expanded configuration by moving the drive member along the hub such that at least one rotatable member

rotates relative to the hub to cause the first and second concave engagement portions to move away from a longitudinal axis of the implant assembly and to seat the first spinous process in the first concave engagement portion and to seat the second spinous process in the second concave engagement portion when the hub and the entire at least one rotatable member are positioned within the subject and positioned directly posterior to the subject's spine.

24. The interspinous apparatus of claim **23**, further comprising:

an implantable inflatable device inflatable from a first unexpanded configuration to a second expanded configuration such that the implantable inflatable device holds the first and second spinous processes while the implant assembly is collapsed and removed from the subject.

25. The interspinous apparatus of claim **23**, wherein the first and second concave engagement portions move away from each other when the implant assembly moves towards the expanded configuration.

26. The interspinous apparatus of claim **23** wherein concave surfaces of the first and second concave engagement portions are positioned to contact the first and second spinous processes.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,211,146 B2
APPLICATION NO. : 13/406433
DATED : December 15, 2015
INVENTOR(S) : Daniel H. Kim

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page

On the page 6, in column 2, under "Other Publications", line 8, delete "Sogittal" and insert -- Sagittal --, therefor.

Specification

In column 1, line 10, delete "STABALIZATION" and insert -- STABILIZATION --, therefor.

In column 2, line 27, delete "spondylolithesis," and insert -- spondylolisthesis, --, therefor.

In column 2, lines 27-28, delete "spondylotlisthesis," and insert -- spondylolisthesis, --, therefor.

In column 3, line 38, delete "6,500178," and insert -- 6,500,178, --, therefor.

In column 5, line 52, delete "district" and insert -- distract --, therefor.

In column 7, line 65, delete "4 cm" and insert -- 4 cm. --, therefor.

In column 12, line 8, delete "(ipsolateral" and insert -- (ipsilateral --, therefor.

In column 12, line 58, delete "disengagable" and insert -- disengageable --, therefor.

Claims

In column 14, line 25, in claim 1, delete "with" and insert -- within --, therefor.

In column 16, line 8, in claim 17, delete "strut," and insert -- struts, --, therefor.

In column 16, line 10, in claim 17, delete "sruts" and insert -- struts --, therefor.

In column 16, line 33, in claim 19, delete "unexpended" and insert -- unexpanded --, therefor.

Signed and Sealed this
Twenty-first Day of June, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office